EDMVS
July 23-24, 2002

General Dose Setting Issues

Questions for the EDMVS:

1. Does the EDMVS agree that a 10% decrease in terminal body weight compared to controls is appropriate as a definition of Maximum Tolerated Dose when evaluating Tier 1 *in vivo* studies of endocrine activity?

2. Does the EDMVS agree that when little or no other information is available from which to estimate appropriate doses for a Tier 1 *in vivo* study, doses should be set via a range-finding study lasting up to the length of the proposed study, in which dose groups are adjusted depending on the presence or absence of adverse effects as soon as the effects are observed?

3. Does the EDMVS agree that dose groups of 2 to 5 animals are appropriate for such a range-finding study?

4. Does the EDMVS agree that dose-setting be validated separately from validation of the assay protocols?